

be pending in this application. The amendments do not add new matter.

**1. Rejection of claims 1-9 and 11 under 35 U.S.C. §§112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph**

The Official Action states that claims 1-9 and 11 have been rejected under 35 U.S.C. §§112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph "because the term 'hydrate' is confusing", because "'hydrate' is unpredictable because there are different hydrates", and "because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds."

**RESPONSE**

Applicants respectfully traverse these rejections. However, solely to remove the basis for these rejections, applicants have amended claims 1-9 and 11 to recite the salts of the claimed compounds, which the Examiner has indicated is enabled.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw these rejections of claims 1-9 and 11.

**2. Rejection of claim 11 under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

The Official Action states under heading #6 on page 5 that

claim 11 is rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lack of enablement. In particular, the Official Action states that "the specification, while being enabling for treating specific diseases, does not reasonably provide enablement for preventing diseases." The Official Action also seems to repeat this rejection under heading #7, but no apparent reason is given why claim 11 is rejected twice under §112, 1<sup>st</sup> paragraph. Accordingly, applicants only address the rejection under heading #6 on page 5 of the Official Action.

Applicants respectfully traverse this rejection. The subject matter of claim 11 is clearly enabled by the specification, when coupled with the knowledge of the ordinary skilled artisan.

The Examiner alleges that a person of ordinary skill in the art would not be enabled to practice the claimed invention of claim 11 since it claims treatment or prevention of gastrointestinal diseases. However, applicants respectfully submit to the Examiner that the ordinary skilled artisan would be fully aware that compounds which are known to have the ability to suppress gastric acid secretion can be used in a **preventative or prophylactic** manner to prevent certain gastrointestinal disorders from occurring.

To provide evidence to support this well-known fact, applicants have filed herewith an Information Disclosure Statement containing several articles. For the Examiner's convenience,

applicants have briefly summarized several of the key points of the articles cited herewith.

In the Lanas, et al. reference "Low-dose aspirin and upper gastrointestinal damage: epidemiology, prevention and treatment", Curr. Med. Res. Opin, 23(1); pp.163-173 (2007), the authors discuss methodologies used to prevent damaging side effects that occur in the upper GI tract as a result of taking low-dose aspirin and concomitant NSAIDs. The abstract in the 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph states that "Administration of a PPI seems the most effective therapy for the prevention and/or relief of [upper GI tract] side effects in at-risk patients". Further, this reference indicates on page 168, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph that "[t]wo co-therapy approaches have been investigated for prevention of upper GI side effects associated with low-dose aspirin therapy", one of which is "acid-suppressive therapies such as H2-receptor antagonists and proton pump inhibitors" which "reduce gastric acid secretion". It was found that "concomitant antisecretory therapy, especially PPI therapy, was associated with a significant reduction in the relative risk of upper GI bleeding". See page 169, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph. Emphasis added.

Accordingly, a person of ordinary skill in the art would be fully apprised of the prophylactic effects of antisecretory compounds, such as those presently claimed, upon reading this

reference.

In the Rey, et al. reference, "Use of antisecretory drugs among consumers of non-steroidal anti-inflammatory drugs in the general population", Ailment Pharmacol. Ther., vol. 24, pp.1585-1592 (2006), the authors make the point that "[p]harmacologic prophylaxis against [gastroduodenal complications such as dyspepsia, peptic ulcer and digestive haemorrhage] is recommended for persons with at least one risk factor. Effective prophylactic strategies include antisecretory drugs...". See page 1586, 1<sup>st</sup> column, 1<sup>st</sup> paragraph. The authors go on to comment that "the general population enjoys little protection against NSAID-related gastroduodenal lesions, because only 20% of those taking NSAIDs received an appropriate prophylactic strategy." See page 1591, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph. Emphasis added.

Accordingly, a person of ordinary skill in the art would be fully apprised of the prophylactic effects of antisecretory compounds, such as those presently claimed, upon reading this reference.

Further, in the Pham, et al. reference "Acid Suppressive Therapy Use on an Inpatient Internal Medicine Service", Ann. Pharmacother., vol. 40, pp. 1261-1266 (2006), the authors make the point that acid suppressants such as proton pump inhibitors are commonly prescribed for indications regarding prophylaxis of

gastric acid secretion, even though this practice is not approved for labeling by the FDA. On page 1262, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph, the authors state that "[n]on-accepted indications included prescribing of acid suppressant medications for low-risk stress ulcer prophylaxis for non-critically ill medical patients; prophylaxis of [peptic ulcer disease] associated with corticosteroids or anticoagulants..." Emphasis added.

As such, it is clear that persons of ordinary skill in the art, i.e. doctors, are currently using antisecretory drugs in the prophylaxis of gastrointestinal disorders. Accordingly, a person of ordinary skill in the art would be fully apprised of the prophylactic effects of antisecretory compounds, such as those presently claimed, upon reading this reference.

Further, Lanza in the reference "A Guideline for the Treatment and Prevention of NSAID-induced Ulcers", The American Journal of Gastroenterology, vol. 93, No. 11 (1998), states that "[t]he overall risk for serious adverse gastrointestinal (GI) events in patients taking NSAIDs is about three times greater than that of controls" and that "[p]roton pump inhibitors are an acceptable alternative for prevention of NSAID-related complications". (See page 2037, 2<sup>nd</sup> column) Lanza also states on page 2040 in column 1, paragraph 2 that "[n]ot unexpectedly, because of its potent acid-inhibiting property, [omeprazole, a PPI] prevents [duodenal ulcer]

in patients taking NSAIDs." Emphasis added.

Again, it is clear that persons of ordinary skill in the art, such as medical doctors, recognize the fact that antisecretory drugs can be used in the prophylaxis of gastrointestinal disorders. Accordingly, a person of ordinary skill in the art would be fully apprised of the prophylactic effects of antisecretory compounds, such as those presently claimed, upon reading this reference.

Two additional references have also been submitted in the IDS which clearly demonstrate a nexus between 1) inhibition of gastric acid secretion and 2) treatment of gastrointestinal disorders. These references are to Majumdar et al. and M. Robinson.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

**CONCLUSION**

In view of the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the pending rejections and allow all pending claims of this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.


Respectfully submitted,

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